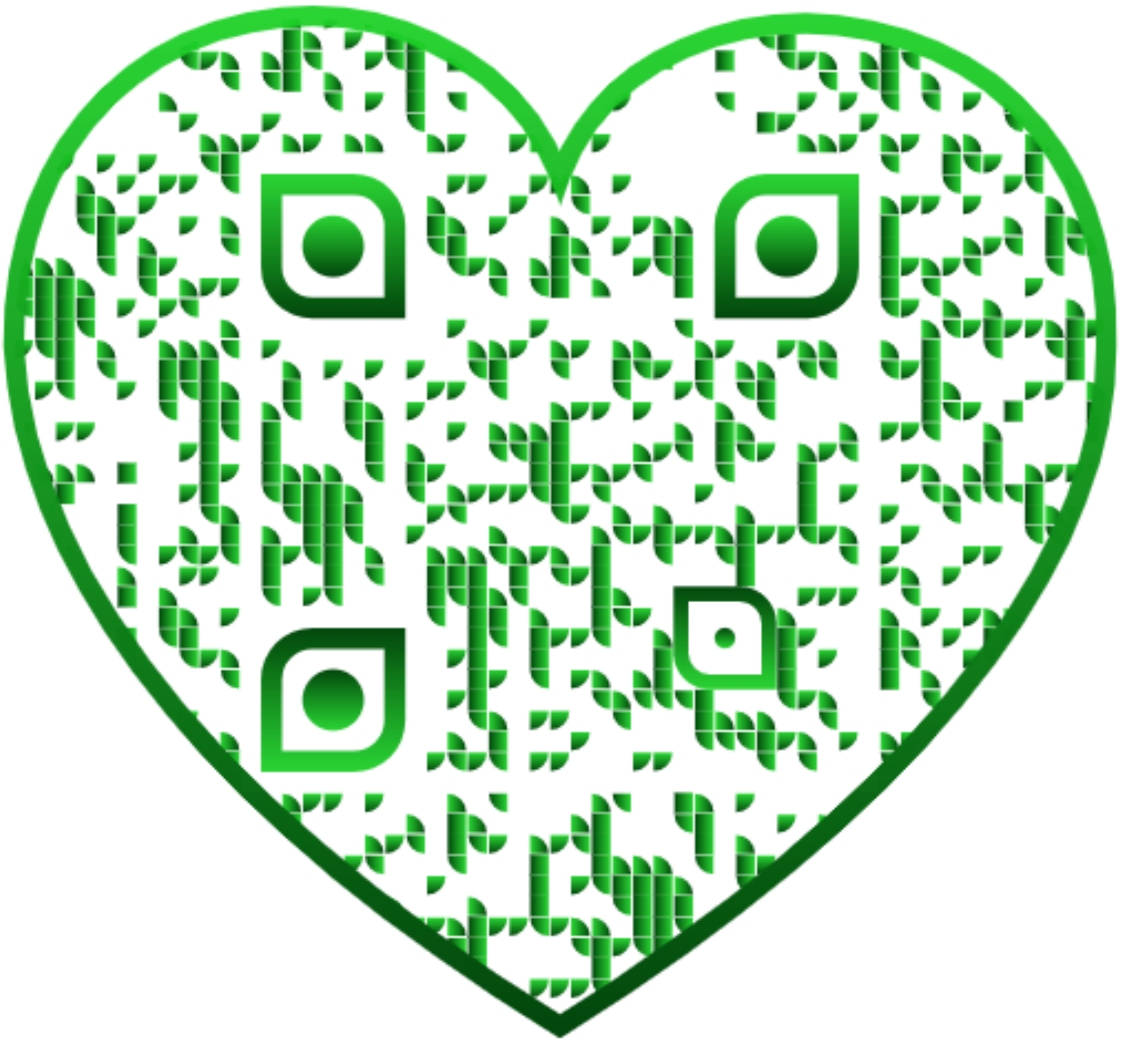
# Drug Storage

Sisay E.



# Session Objectives

- At the end of this session, students will be able to:
  - Describe goals of proper drug storage
  - List the stages of stock movement in the store
  - Discuss types and aims of zoning in the stock
  - Discuss the various aspects of good storage practices
  - Discuss the special storage conditions
  - Identify storage problems and suggest adequate solutions

# Introduction

- Product storage is an important activities in the supply chain management of medical products
- Products are stored at every facility in the pipeline;
  - Almost everyone working in the supply chain is responsible for product storage
- Storage ensures the **physical integrity** and **safety** of products and their packaging, throughout the various storage facilities, until they are dispensed to clients.

# Goals of Proper Drug Storage

- Drugs are stored in specially designed secure area in order to:
  - Avoid contamination or deterioration
  - Maintain integrity of packaging
  - Avoid disfiguration of labels
  - Prevent or reduce pilferage, theft or losses
  - Prevent infestation of pests
  - ➔ Effective use of information is a key to achieving these goals

# Key Storage Activities

- Regardless of storage facility size; from a small health center to a central warehouse; the main operational activities for storage are very similar.
- How complex these activities become will vary based on:
  - The volume of products to be managed
  - Storage facility size
  - Particular requirements, such as cold storage.

# Steps in pharmaceutical storage and key storage activities

- **Flow of Stocks: Six Stages**
  - Receiving
  - Storage
  - Allocation of stock (Order allocation)
  - Order Picking
  - Order assembly
  - Dispatch/delivery

# Key storage activities..

- **Material receiving and incoming inspection:**
  - This activity occurs during the unloading of vehicles
  - Includes the visual inspection of delivered packages to ensure that products were not damaged during transport.
  - Verify the quantities of products received against the packing slip or shipping invoice.
  - Report any discrepancy

# Key storage activities…

- **Put away:**
  - This process includes moving products from the unloading dock, or receiving area, after they are released for storage; and assigning them to their designated storage area (rack, shelf, floor, etc.)
  - It is important that every product moved into or out of the racks, shelves, or any storage area is correctly recorded on the stock keeping records; an inventory control system helps you manage them.
  - Whether the process is manual or automated, the best practice is to put away products the same day they are received

# Key storage activities…

- **Picking and packing**
  - To fill shipping requests (or picking lists), products must be located, pulled from inventory, and prepared for shipment.
  - In some cases, products need to be packed into shipment containers or palletized; and, sometimes, bundled with other products into kits before being shipped.
  - When any packing or repacking activity takes place, the new package must be labeled correctly

# Key storage activities…

- **Shipping**:
  - To guarantee good shipping accuracy, the list of products and their quantities must be checked against shipping orders, or requests, prior to preparing the required shipping documents and loading of the cargo for transport
  - To avoid damage during transit, products must be arranged and secured within the vehicle using the requirements and conditions for adequate loading and transport

# Key storage activities: Visual Inspection

- **Visual inspection**
  - It is the process of examining products and their packaging to detect obvious problems in product quality
- **Conducting Visual Inspection:**
  - Package and product integrity
  - Manufacturing defects
  - Labeling

# Key storage activities: Visual Inspection…

- **Conduct a visual inspection when any of the following occur:**

  - ✓ Receive products from the manufacturer (usually at the central level)
  - ✓ Warehouse or health facility receives supplies
  - ✓ Conduct a physical inventory count
  - ✓ Dispense products to a client
  - ✓ Issue products from one level to another
  - ✓ Receive complaints from lower levels or customers
  - ✓ Products are about to expire
  - ✓ Products show signs of damage
  - ✓ Products have been kept under improper storage conditions

# Key storage activities : Physical inventory count

- **A physical inventory count enables:**
  - Confirm how much stock have and whether forms the stock card are being completed correctly
  - Used to compare actual stock on hand for each commodity with the amount recorded on the stock card
  - For quality assurance, a physical inventory count is also an opportunity to inspect the products visually

# Physical inventory count…

- Frequency of physical inventory counts
  - May be governed by local regulations
- Large central warehouses should conduct a physical inventory count at least once a year
- Some options for conducting inventory counts include:
  - **Cycle counting**
    - Regular cycle counting can keep physical inventory up-to-date without disrupting store operations.

# Physical inventory count…

- **Vital, Essential, or nonessential (VEN) analysis**
  - Involves counting the most essential, or most expensive items
  - This analysis categorizes products as vital, essential, or nonessential, enabling to assess stocks of vital items more often than nonessential items
- **ABC analysis**
  - Divide products into three categories, **based on monetary value.**

# Designing pharmaceutical warehouse

- **During pharmaceutical store Layout and design**
  - Develop a demand forecast
  - Determine each item‘s order quantity
  - Convert units into cubic footage requirements
  - Allow for growth
  - Allow for adequate aisle space for materials handling equipment
  - Provide for the transportation interface
  - Provide for order-picking space
  - Provide storage space
  - Provide recouping, office, and miscellaneous spaces

# Storage Space requirements

- Proper storage includes the effective use of storage space
- To determine space requirements, consider the following:
  - Total stored pallet equivalents, by commodity, based on a peak month
  - Stored pallet orientation
  - Required space for receiving, inspection, and quarantine
  - Required space for picking, packing, and shipping
  - Type of storage media, per commodity (i.e., pallet rack, gravity flow rack, shelving)
  - Required operation aisle distances
  - Type of material handling equipment required.

# Warehouse Layout and its Relation to Pharmaceuticals/ Materials Flow

- The layout is the framework in which the overall storage space arrangement is developed
- The complete floor plan shows the actual manner in which the gross space with in the storage area is used
- The plan shows the division of the space to the storage, receiving, shipping areas, main aisles, crosses aisles, fire aisles, and offices.
- It enables planning for the effective use of space
- It enables quick response-essential to economic warehouse operations

# Principles of Stores Layout Plan

- **Item similarity:**
  - e.g., similar handling requirements stored together
- **Item popularity:**
  - **Fastest moving bulk stock**s
    - Should be stored in areas that allow quick and easy access to reduce travel of materials handling equipment and Stock Selection personnel
  - **Fast- moving Bin stocks**
    - Should be easily accessible to expedite stock selection and replenishment

# Dejunking and Organizing storage spaces

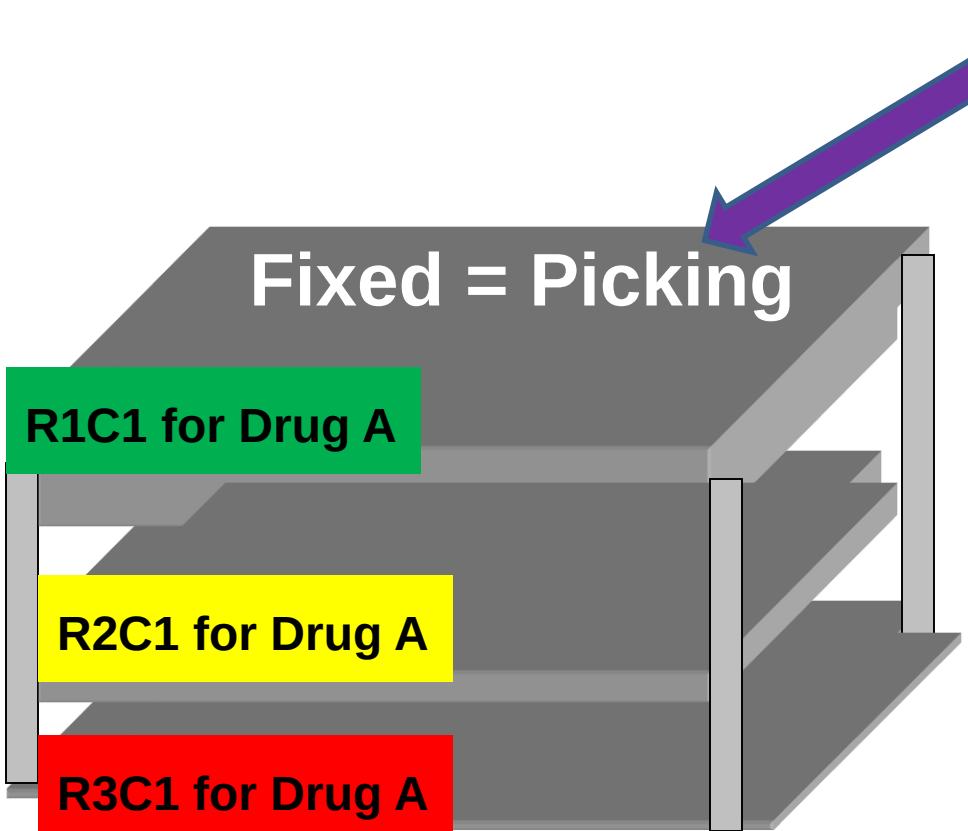
- Organize pharmaceuticals on their shelves according to First-to-expire, first-out (FEFO)
  - Put supplies that will expire sooner in front of or on top of pharmaceuticals that will expire later
- Organize the storage area in an orderly manner so health supplies can be found easily and re-stocked easily.
- Designate a specific space for temporary storage of unusable items before their disposal.

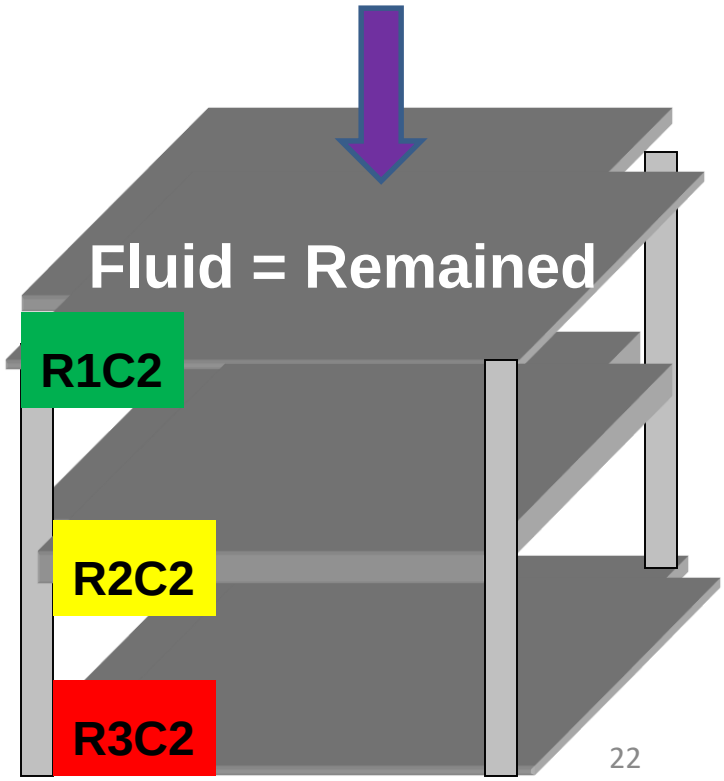
# Organizing storage spaces….

- Logical organization of pharmaceuticals in the store:
  - Organize the storage area into zones as needed:
    - Cold storage area for vaccines and other supplies requiring cold storage
    - Secure room or locked cage for narcotics and controlled substances
    - Zone in which to store flammable materials, ideally in a separate building or room

# Stock Location Within a Zone

- Fixed Location
- Fluid Location
- Semi-fluid Location



# General Storage Guidelines

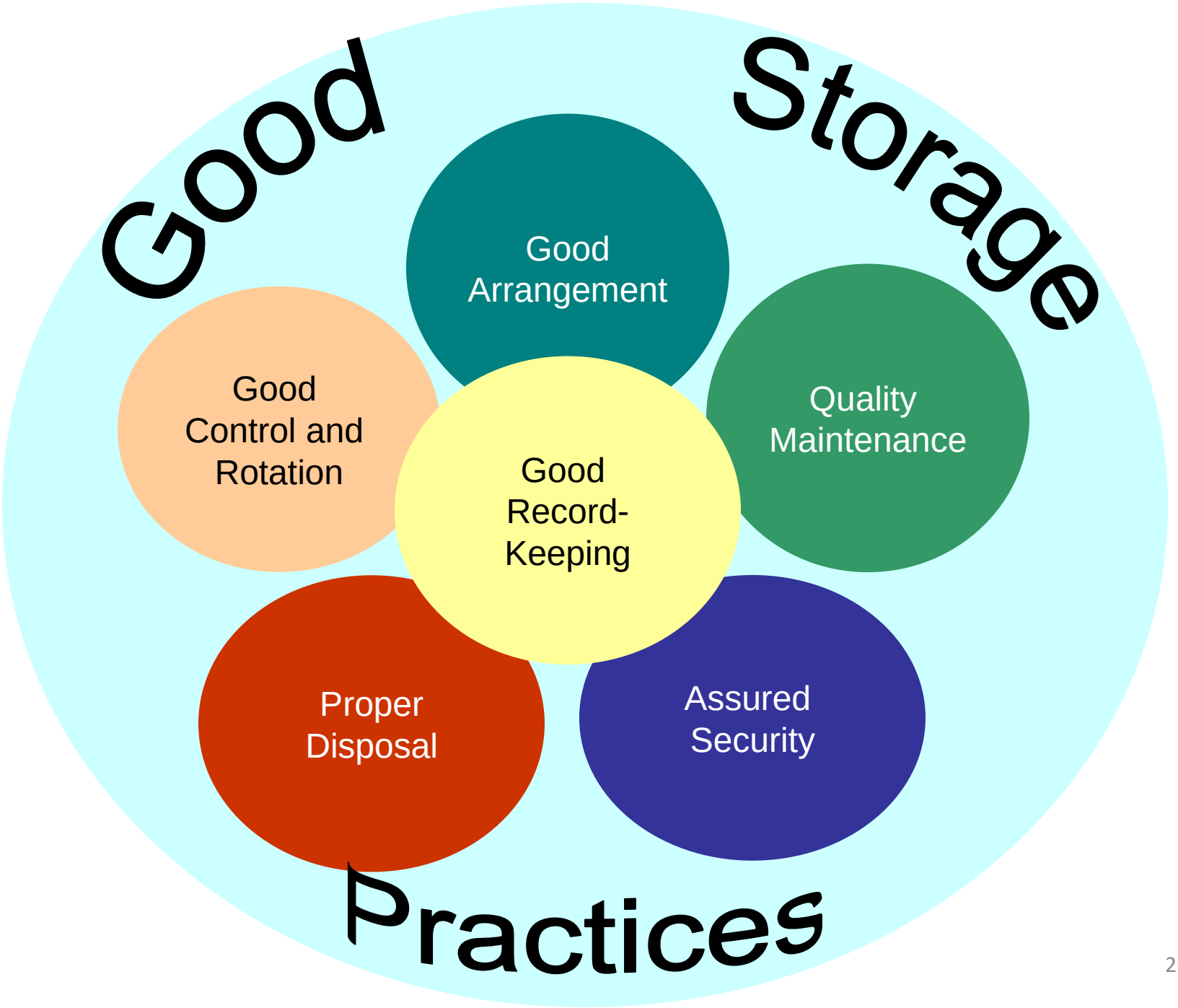
- Pharmaceutical are to be stored under conditions that prevent contamination and, deterioration
- Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured
- Supplies should be protected from sun, heat, and water
  - Follow manufacturer recommendations for storing supplies
    - This information is usually printed on the product carton and boxes

# General Storage Guidelines…

- The following are general storage guidelines for pharmaceuticals
  - Clean and disinfect storeroom regularly
  - Store supplies in a dry, well-lit, and well-ventilated storeroom, out of direct sunlight
  - Secure the storeroom from water penetration
  - Ensure that fire safety equipment is available and accessible, and that personnel are trained to use it
  - Store latex products away from electric motors and fluorescent lights
  - Maintain cold storage, including a cold chain, for commodities that require it.
  - Keep narcotics and other controlled substances in a locked area.

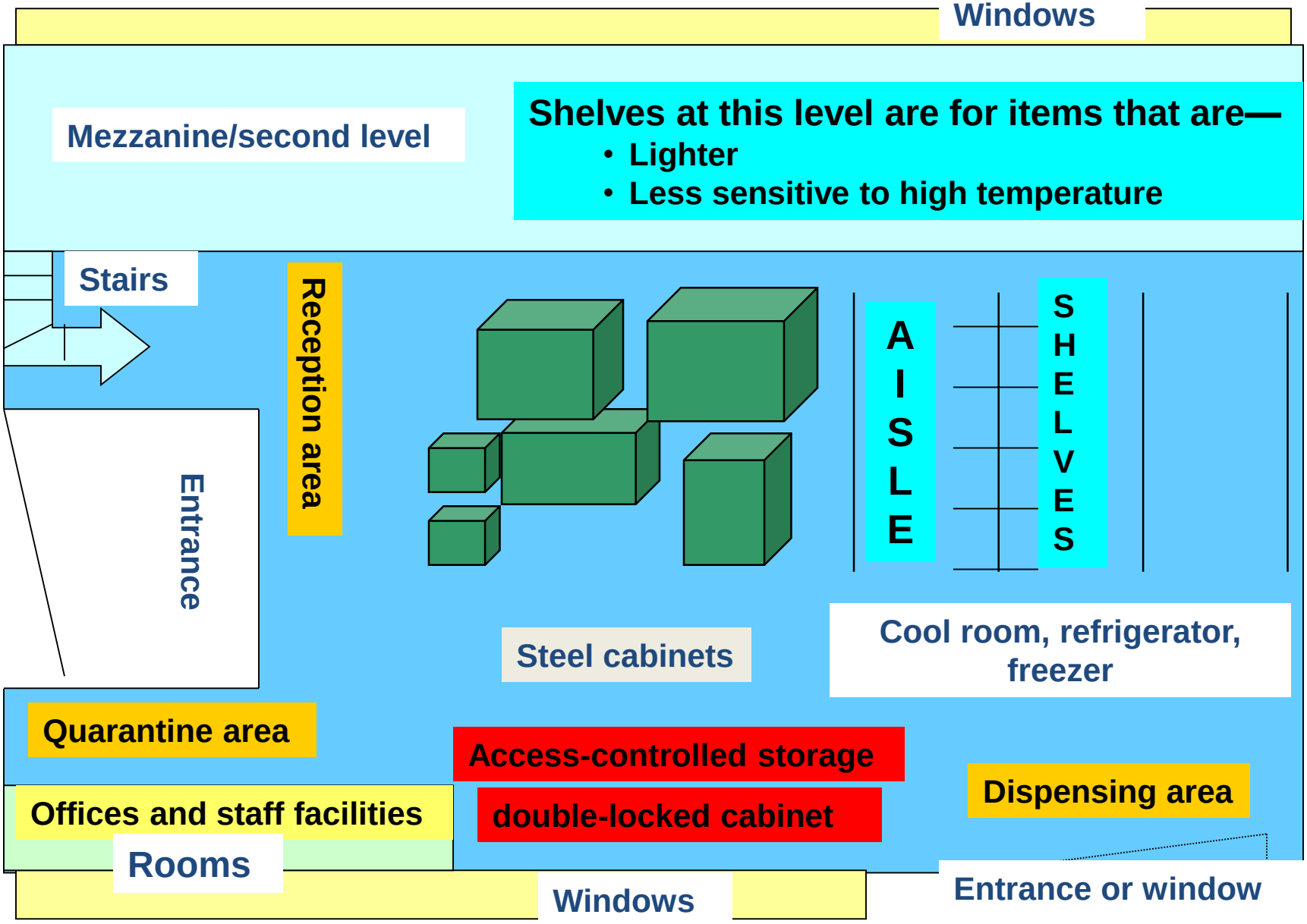
# General Storage Guidelines…

- Store flammable products separately, using appropriate safety precautions.
- Stack cartons at least 10 cm (4 in) off the floor, 30 cm (1 ft) away from the walls and other stacks, and no more than 2.5 m (8 ft) high.
- Store medical supplies separately, away from insecticides, chemicals, old files, office supplies, and other materials.
- Arrange cartons so that arrows point up; ensure that identification labels, expiry dates, and manufacturing dates are visible.
- Store supplies in a manner accessible for FEFO, counting, and general management.
- Separate and dispose of damaged or expired products without delay


Good Storage
Good Arrangement
Good Control and Rotation
Quality Maintenance
Good Record-Keeping
Proper Disposal
Assured Security
Practices

Good
Arrangement

# How to Arrange the Storage Area (2)



# Basic Storage Systems

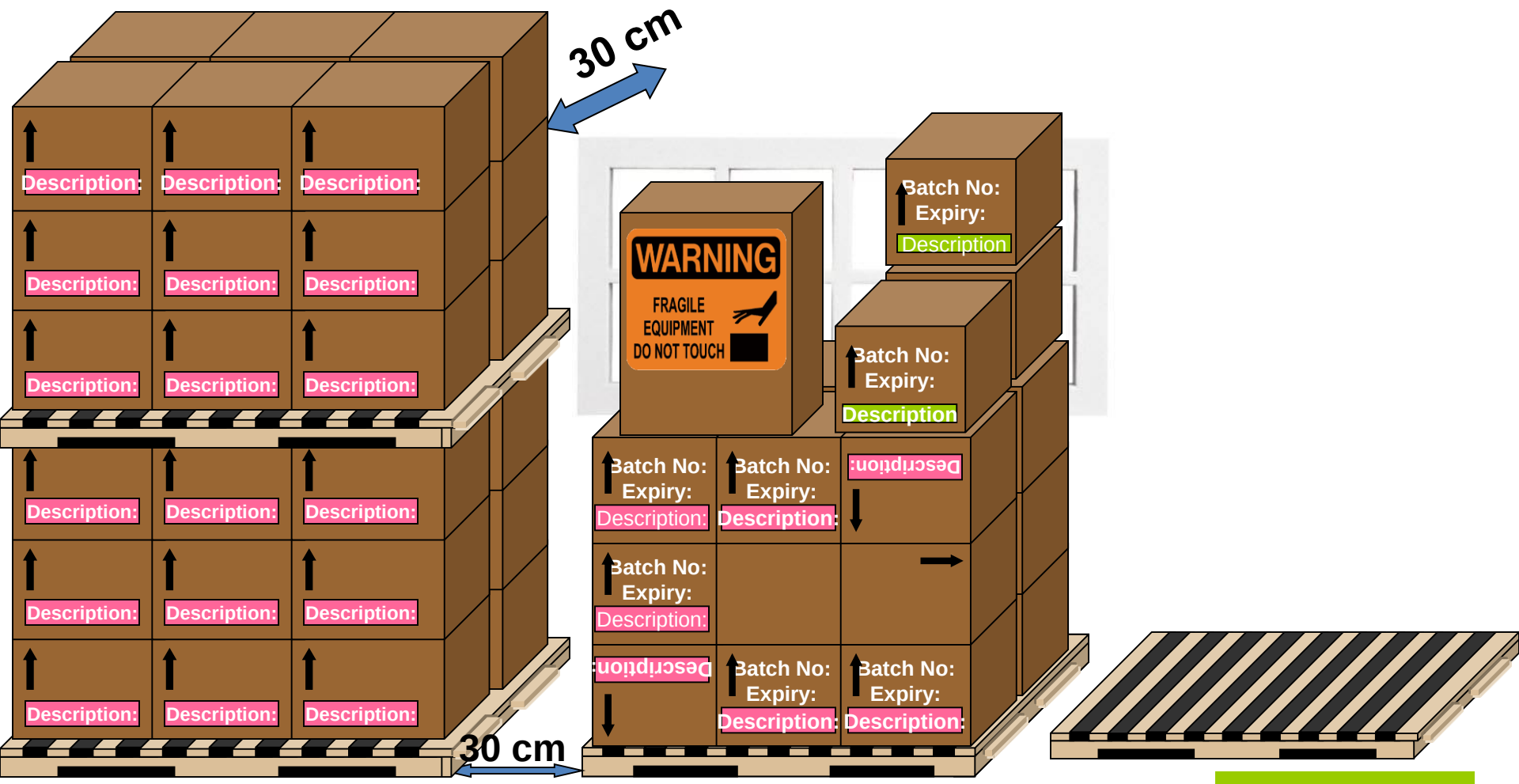
Direct storage of cartons on the warehouse floor must be avoided

1. Shelves
2. Floor pallets
3. Block-stacked pallets
4. Pallet racking

# Shelves: Basic Rules

- Heavy and fragile items on the lower shelves
- Frequently picked items at waist height
- Extra stock on the upper shelves (if it is not too heavy)
- Boxes tidy and closed as much as possible

# Block-stacked and Floor Pallets: Basic Rules




***Block-stacked pallets***

- Light goods
- Items without expiry dates (longer
- Items with very high turnover

***Floor pallets***

# Pallet racking

# Load Handling

- Correct handling equipment
  - reduces risk of damage to workers and to goods

Forklift

Hand pallet truck

Mechanical Hand-lift stacker

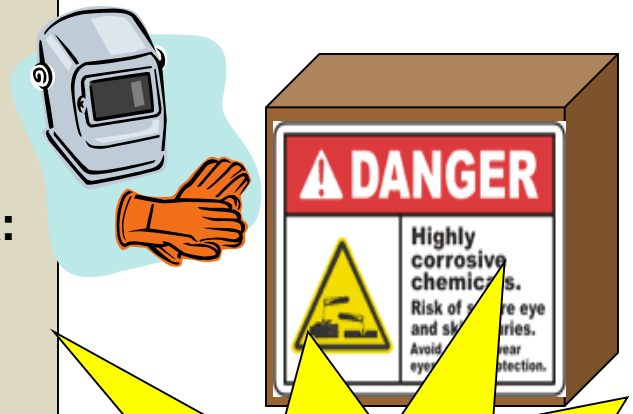
# How to Classify the Stock

- Pharmacological category
- Alphabetical order
- Level of use/system level
- Frequency of use
- Dosage form
- Random bin
- Commodity code

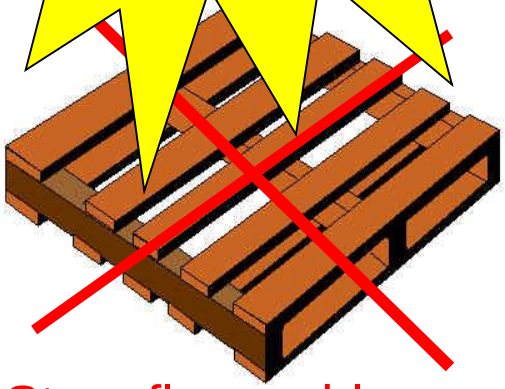
# Special Precautions: Flammables and Corrosives

Never store in direct sunlight

- **Always store flammables in their original containers**
- **Large amount of stock: Use a location away from main storeroom**
- **Small amount of stock: Use a steel cabinet that will contain any spillage**
- **Display international hazard symbol**
- **Use coolest location**
- ✓ **Control evaporation rate**
- ✓ **Avoid build-up of pressure**
- **Use industrial gloves and eye glasses to handle corrosives**




Do not store flammables with corrosives

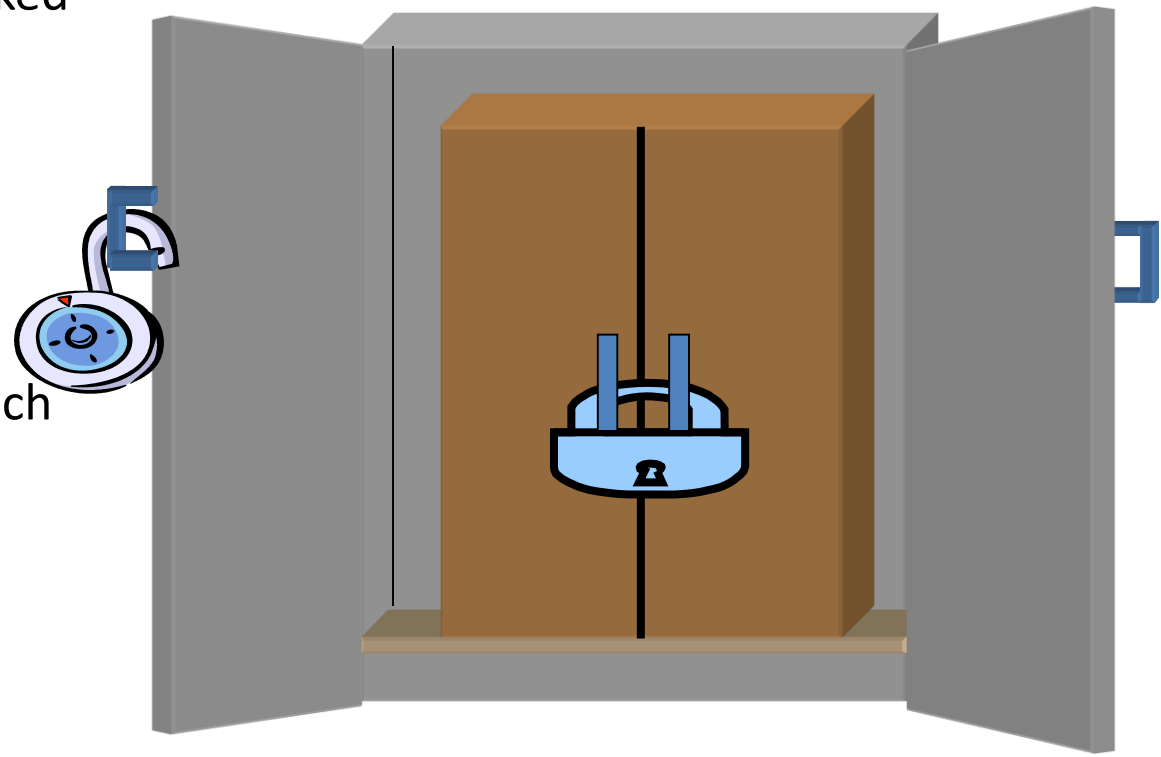


Store flammables away from pallets

# Special Precautions: Controlled Substances

- **Double-locked cabinet**
- Red warning light or warning bell that activate when unlocked

- Special register recording—
  - Special prescription
  - Signatures at “handover” and “takeover”
  - Physical counting after each entry
- Independent audit



# Special Precautions: Valuable Items

- Are scarce, expensive, and in high demand

- **Example: ARVs**

→ Keep locked

→ Restricted access

→ Special register recording

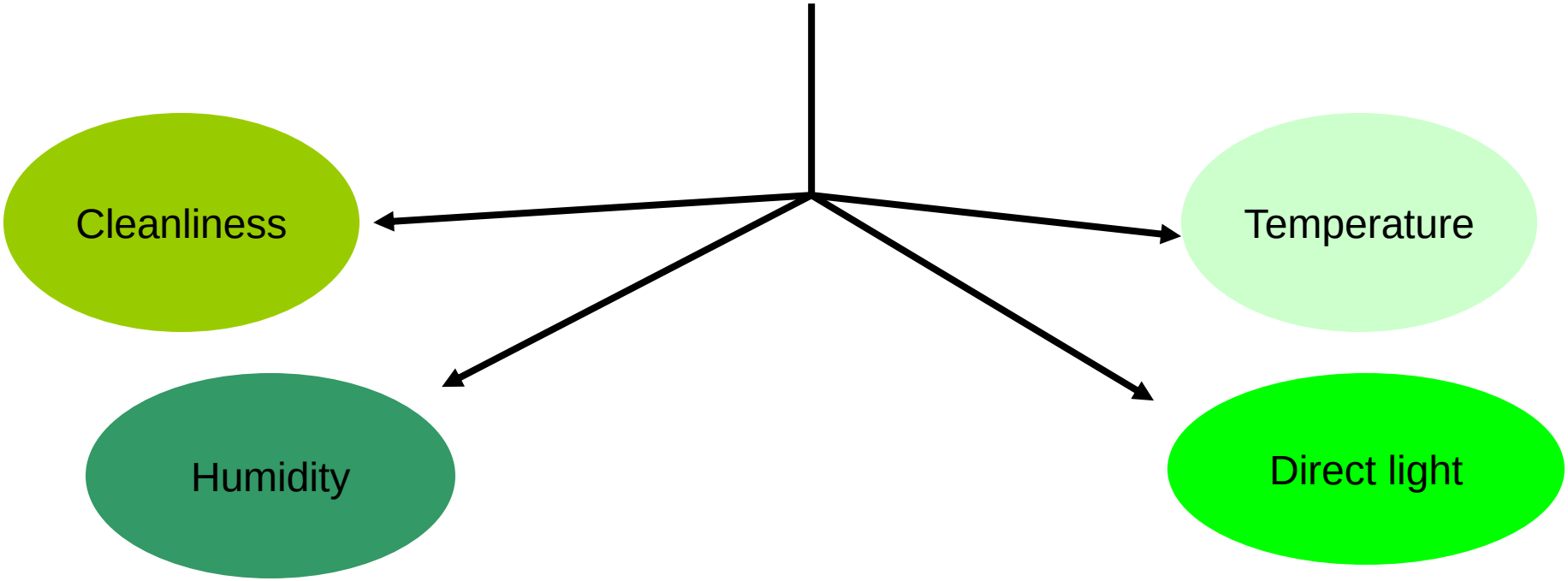
Locked wire Cage for large stock of ARVs

Locked cupboard for smaller stock of ARVs

Quality
Maintenance

# Maintain Quality

**Inside the storage area ……. what can affect the quality of the medicines????**



# Maintain Quality: Temperature

☞Monitor temp of different zone  regularly

**You can be a thermometer.**

**If you feel hot in your storeroom, your medicines are probably hot, too.**

# Temperature: Storeroom

☞ Follow the manufacturer's storage instructions

- **If No** apply "normal storage conditions"

☞ Avoid extreme temperatures; they damage products

# Common terms relate to temperature

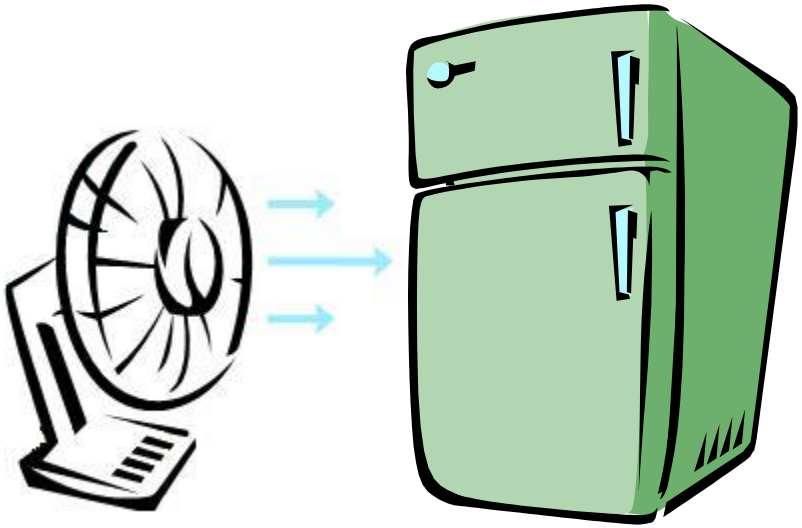
- Store frozen: stored at –20°C (4°F)
- Store at Refrigerator/cold: 2°C – 8°C (36°– 46°F)
- Keep cool: Store between 8°C – 15°C (45° – 59°F)
- Store at room temperature:  15°C – 25°C (59°F – 77°F)
- Store at ambient temperature = “room temperature” or “normal storage conditions”

# Temperature Cont'd

| On the label | Means |
|---|---|
| "Do not store over 30 °C" | from +2 °C to +30 °C |
| "Do not store over 25 °C" | from +2 °C to +25 °C |
| "Do not store over 15 °C" | from +2 °C to +15 °C |
| "Do not store over 8 °C" | from +2 °C to +8 °C |
| "Do not store below 8 °C" | from +8 °C to +25 °C |
| "Protect from moisture" | no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moisture resistant container. |
| "Protect from light" | to be provided to the patient in a light-resistant container. |

# Temperature: Cold Storage

- Record the daily temperature in the refrigerator
- Maintain the recommended refrigerator temperature: 2–8°C
- Keep refrigerators in shady, ventilated area



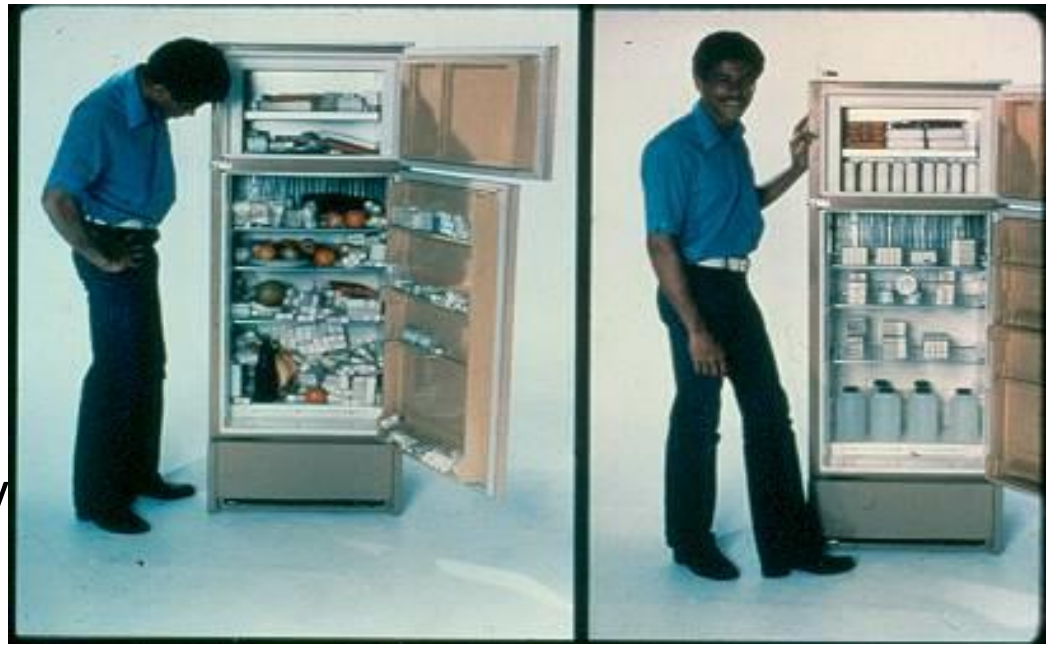
# Temperature: Cold Storage

**Keep good air circulation**

**Poor air circulation means NO refrigeration**

# Temperature: Cold Storage

- Minimize the frequency and duration of opening the refrigerator
- Keep the refrigerator well organized
- Use the refrigerator exclusively for medical products, not for staff food

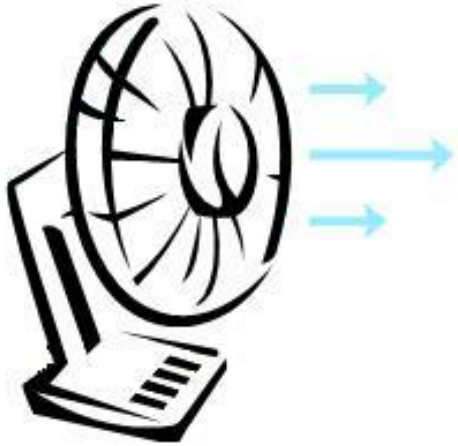


# Quality: Humidity and Ventilation

- In humid climates, **dehumidifiers** (preventing moisture damage)
  - If the storeroom has no dehumidifier, use **ventilating fans**, expose the area to light, or **open the windows** if possible

Light

Open window



Fan

Dehumidifiers

# Quality: Direct Light

**Storage Options**

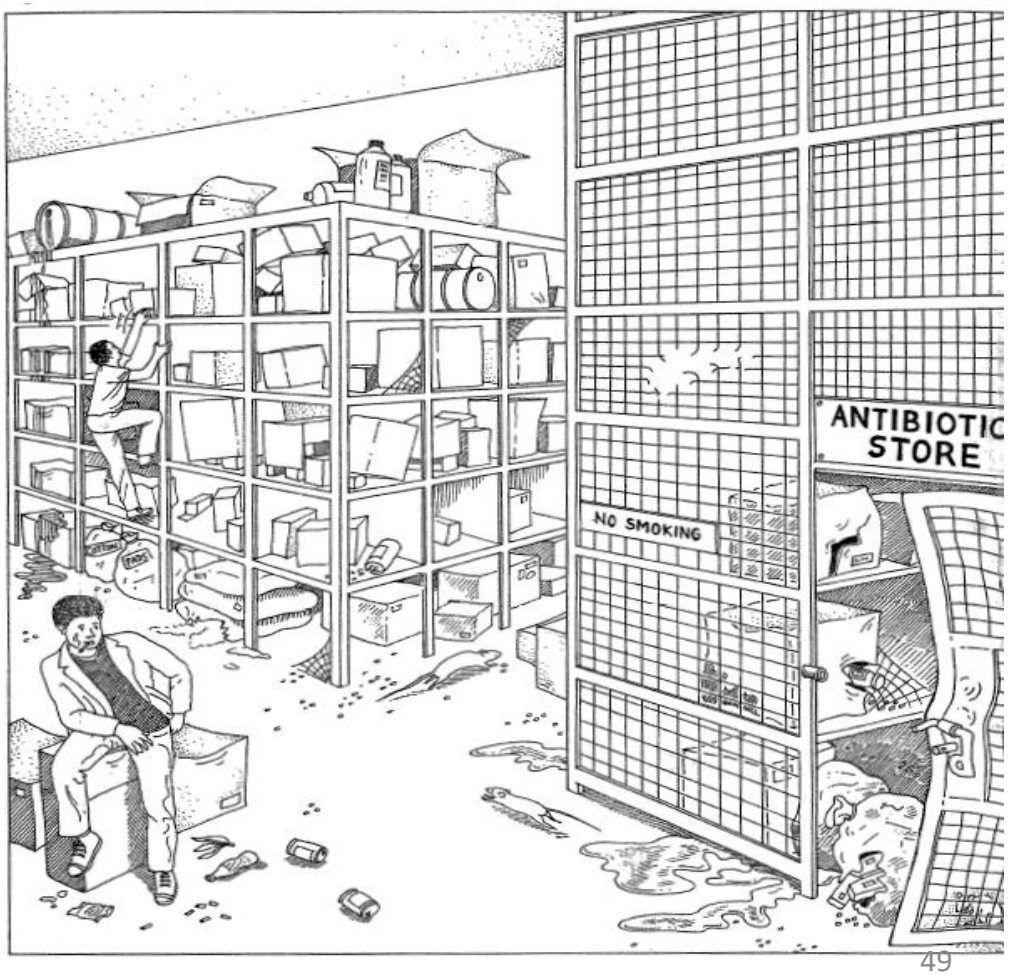
- Keep liquids in tinted glass
- Keep light-sensitive items in their original packaging
- Protect from sun
  - Keep in a cupboard
  - Keep in shady corner
  - Keep in closed boxes

**X-ray films**

**Tinted glass**

# Quality: Cleanliness

- Post a schedule and instructions for cleaning
- Clean the floor and the shelves regularly
- Dispose of garbage often
- Keep the area outside the facility clean
- Schedule regular inspection (senior staff)



# Staff Facilities and Housekeeping

- Provide adequate staff facilities
- Prohibit the consumption of food in areas where stock items are stored
- Clean the storeroom areas regularly
- If needed, implement pest control measures such as poison, but use proper precautions

Assured
Security

# Security: General Rules

- Use double doors and double locks on entrance
- Use burglar bars on windows
- Control entry to the pharmacy
- Set rules so that all staff who handle supplies are equally accountable for their actions
- Maintain good control of stock cards and registries to detect theft

Proper
Disposal

# Pharmaceutical Waste Disposal

- **Health-care waste:** Products generated by health care facilities during a variety of activities—Dx, Tx, research and immunization
  - Hazardous (posing a risk) waste: 75% and 90% of HCW
  - General (non-hazardous) waste: 10% and 25% of HCW

# Pharmaceutical wastes

☒Pharmaceutical waste (Unfit medicines) includes;

- Expired Pharmaceuticals
- Damaged, Improperly sealed, improperly stored and/or labeled (Expired or unexpired)
- Counterfeited, substandard
- Prohibited or outdated products
- Unauthorized

# Pharmaceutical wastes Cont'd

- Some hazardous pharmaceuticals can cause wastes with any of the following characteristics

**Ignitability**

- Waste formulations that contains 24% alcohol or more by volume and having a flashpoint of < 60 $^{o}$C

**Corrosivity**

- Any waste which has a pH of less than or equal to 2 (highly acidic) or greater than or equal to 12.5 (highly basic)

# Pharmaceutical wastes Cont'd

- **Reactivity:**
  - it is normally unstable under "normal" conditions
  - it reacts violently with water
  - forms potentially explosive mixtures with water
  - it generates toxic gases, vapors or fumes when mixed with water
- **Toxicity:**
  - If an extract of the waste is found to contain certain heavy metals above specified levels/regulatory levels

    E.g. Barium, Cadmium, Selenium

# Disposal of Pharmaceutical Wastes

- **Expired medicines:**
  - may no longer be effective and may be dangerous
  - should be placed in a designated salvage area
  - A written record of all stock consigned to this area should be maintained
  - must be destroyed in accordance with local regulations

# Steps to be taken

A series of steps need to be taken when disposing of unwanted pharmaceuticals:

1. Decision
2. Approval
3. Planning
4. Forming work teams
5. Health and safety of work teams
6. Sorting
7. Disposal
8. Security

## Annex III: Medicines Waste Register Book

| No. | Description of Medicines Wastes (generic & brand name, strength and dosage form) | Unit Type and Size | Quantity | Batch Number | Expiry Date | Reason for Disposal (expired, damaged, spilled, etc) | Manufacturer/ Supplier | Store Location | Purchase Value |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |
| 4 | | | | | | | | | |
| 5 | | | | | | | | | |
| 6 | | | | | | | | | |

## Annex IV: Medicines Waste Disposal Application Form

**To: Appropriate Organ (when the applicant has its own disposal facility)**

**Subject: <u>Request for Medicines Waste Disposal</u>**

I/We ----------of (address) ----------undertaking the business of (specify) ----------
---------- hereby apply for disposal of medicines waste.

License Number----------issued on----------

Location of Business----------

Name of person in charge ----------

Reason for disposal----------

Weight (in Kg) ----------

Value (in Birr) ----------

Attached herewith is the list of products to be disposed of.

**Declaration:**

I certify that the information provided in the application form is true and correct. Date of application----------

Signature of Applicant----------Stamp----------

## Annex V: Medicines Waste Disposal Application Form

**To: Disposal Firm (**when the applicant is a health institution looking for disposal service)

**Subject: <u>Request for Medicines Waste Disposal</u>**

I/We ----------of (address) ----------undertaking the business of (specify) ----------

---------- hereby apply for disposal of medicines waste.

License Number----------issued on----------

Location of Business----------

Name of person in charge ----------

Reason for disposal----------

Weight (in Kg) ----------

Value (in Birr) ----------

Attached herewith is the list of products to be disposed of.

**Declaration:**

I certify that the information provided in the application form is true and correct.

Date of application---------- Signature of Applicant----------Stamp----------

**Cc:**

To appropriate organ

| **Annex VII: Certificate of Medicines Waste Disposal for Health Institution** | Name of appropriate organ<br><br>Date of Disposal: |
|---|---|

We undersigned below would like to certify that (name of disposal firm) _____with license number _____ located at_____ has disposed medicines wastes listed below under the direct supervision of (name of inspector) _____and disposal committee of this health institution.

| No. | Description of Medicines Wastes (generic & brand name, strength & dosage form) | Unit type and size | Quantity | Batch Number | Expiry Date | Reason for Disposal | Disposal Method | Manufacturer/ Supplier | Country of Origin |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |
| 4 | | | | | | | | | |
| 5 | | | | | | | | | |
| 6 | | | | | | | | | |
| 7 | | | | | | | | | |
| 8 | | | | | | | | | |
| 9 | | | | | | | | | |
| 10 | | | | | | | | | |
| Name and Signature of Inspector | | | | | Name and Signature of appropriate organ | | | | |

*Copy Distribution: 1st copy to health institution and 2nd copy to* appropriate organ

| Name and Address of Disposal Firm | **Annex VIII: Certificate of Medicines Waste Disposal for Disposal Firm** | Name and address of appropriate organ<br><br>Date of Disposal: |
|---|---|---|

We undersigned below would like to certify that (name of disposal firm) _____ with license number_____ located at_____ has disposed medicines wastes listed below for (name of disposal service requester) _____ license number _____located at_____ under the direct supervision of (name of inspector)_____

| No. | Description of Medicines Wastes (generic & brand name, strength & dosage form) | Unit type and size | Quantity | Batch Number | Expiry Date | Reason for Disposal | Disposal Method | Manufacturer/Supplied or Purchased from |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
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| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |

| Name and Signature of Inspector | Name and Signature of appropriate organ |
|---|---|

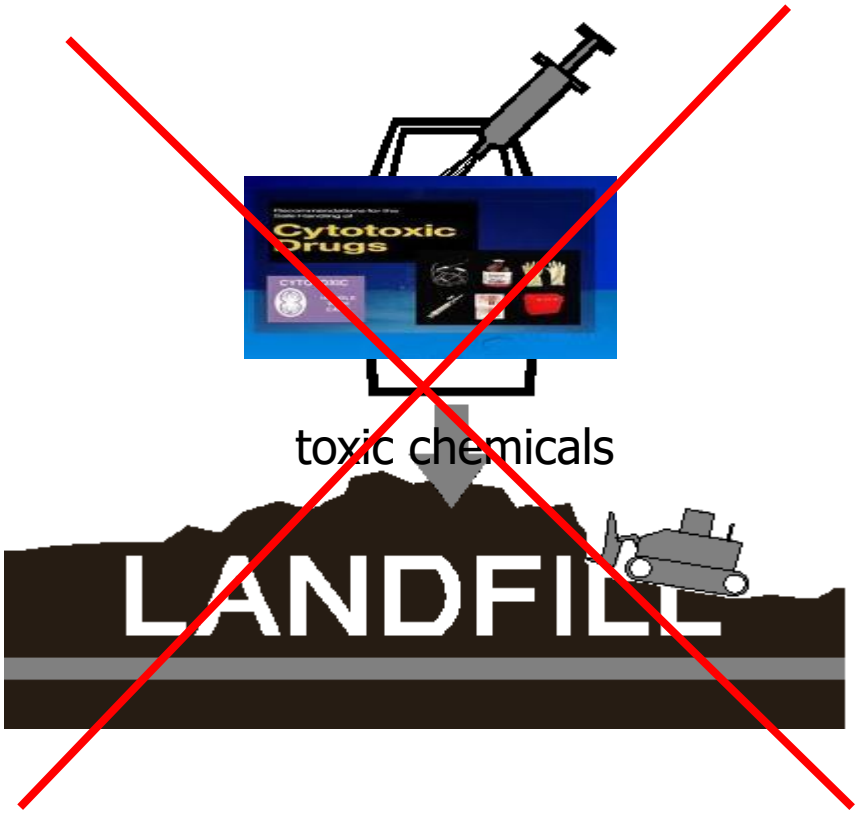
*Copy Distribution: 1st copy to disposal firm,* 2nd copy to health institution (disposal service requester) and 3rd copy appropriate organ

# Disposal Methods

- Return to donor or manufacturer: through a **"take-back"** program

- **Landfill:** Place waste directly to disposal site (without prior treatment)

  ☞ **have potential to leaching toxic component into the groundwater**



# Disposal methods Cont'd

- **Encapsulation :**
  - Immobilizing pharmaceuticals in a solid block within plastic or steel drum
  - Filled to 75% capacity; the rest by mixture of lime, cement and water in proportions 15:15:5 (by weight)
- **Inertization:**
  - Grinded pharmaceutical waste (Remove packaging material): 65%
  - Lime: 15%
  - Cement: 15%
  - Water: 5% or more to form a homogeneous paste

# Disposal methods Cont'd

- **Burning in open containers:**

- As last resort, as toxic pollutants may be released into the air
- Paper and cardboard packaging, if they are not to be recycled

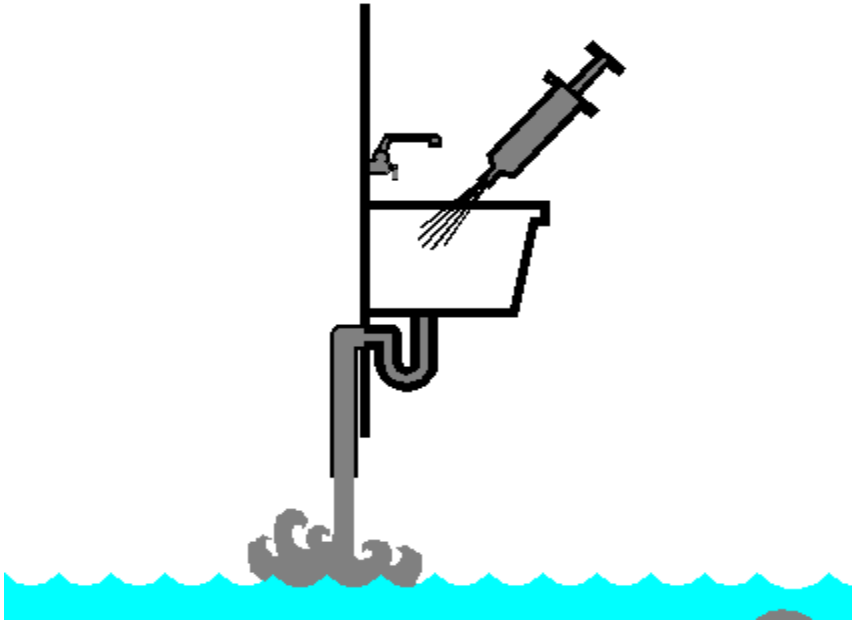
# Disposal methods Cont'd

- **Incineration (Medium and high temp):**
- controlled heating processes to convert a waste to less bulky, less toxic or less noxious

**Portable incinerator**

# Disposal methods Cont'd

- **Sewer system:**
  - diluted and flushed in to sewer in small quantity
  - Only non hazardous: Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised)



# Waste Disposal Method Cont'd

- **Chemical decomposition:**
  - Used if no other options ,followed by land fill
  - Not recommended unless special chemical expertise available
  - Tedious and time consuming, and stocks of the chemicals used in treatment must be made available at all times
  - Not practical for quantities over 50 kg, as even small consignments need to be treated through repeated application of this method

# Summary of pharmaceutical categories and disposal methods

| Category | Disposal methods | Comments |
|---|---|---|
| **Solids** | Landfill | No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill |
| **Semi-solids** | Waste encapsulation | |
| **Powders** | Waste inertization , Medium and high temperature incineration | |
| **Liquids** | Sewer, Incineration | Antineoplastics not to sewer |
| **Ampoules** | Crush ampoules and flush diluted fluid to Sewer | Antineoplastics not to sewer |

# Summary of disposal Cont'd

| Category | Disposal methods | Comments |
|---|---|---|
| **Anti-infective And disinfectants** | Waste encapsulation<br>Waste inertization<br>Incineration | No undiluted disinfectants to sewers or water courses |
| **Antineoplastics** | Return to donor or manufacturer<br>Waste encapsulation<br>Waste inertization<br>Incineration | Not to landfill unless encapsulated<br>Not to sewer<br>No medium temperature incineration |
| **Controlled drugs** | Waste encapsulation<br>Waste inertization<br>Incineration | Not to landfill unless encapsulated |
| **Aerosol** | Landfill, Waste encapsulation | Not to be burnt: may explode |

# Consequences of Improper Disposal

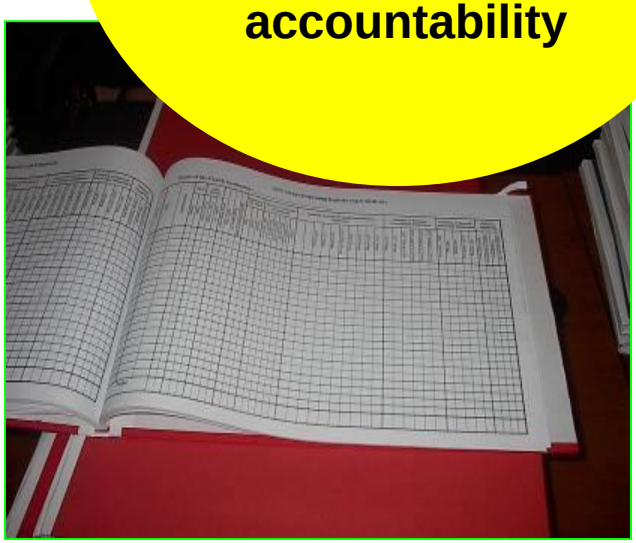
- Contamination of water
- Air pollution/ release of toxic pollutants
- Expired drugs may come into the hands of scavengers and diverted to the market for resale and misuse

# *Good* Control and *Rotation*

# Ensuring Good Control of Stock through Good Record-Keeping

- Stock /Bin cards
- Vertical file cards
- Kardex system
- Ledgers or stock books
- Computer

**Keep at least <u>two</u> stock records of each item to ensure accuracy and accountability**



# Ensuring Good Control of Stock through Regular Physical Inventory

- **Complete physical inventory/ Annual counting :** Covers all the items
- **Cyclic or Continuous physical inventory:** Covers certain number and types of items

# Adequate Stock Rotation: Minimize Losses Due to Expired Medicines

- Monitor expiry dates closely
- Use **FEFO** policy
- Return excess stock items to warehouses for redistribution

THESE MUST BE FRESH THEY CAME IN LAST WEEK..
AMOXY EXPIRY FEB 1995
AMOXY EXPIRY APR 1996
AMOXY EXPIRY JUN 1997
AMOXY EXPIRY SEPT 1998
SULFA EXPIRY JAN 1995
SULFA EXPIRY MAY 1996
SULFA EXPIRY FEB 1997
SULFA EXPIRY AUG 1998

- **Distribution:**
  - The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent

# General principles of distribution

- All parties in distribution chain have a responsibility to ensure the quality of the products and that the integrity of the distribution chain is maintained from the manufacturer to the entity responsible for dispensing
- GDP principles should be included in national legislation and guidelines
- Principles apply forward AND backward in the supply chain
- Collaboration between regulators, law enforcement, customs agencies, manufacturers, distributors, pharmacies,